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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,900	09/30/2003	Charles M. Buchanan	05015.0366U4	6139

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EXAMINER	
MAIER, LEIGH C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,900	BUCHANAN ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 26-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-22 and 26-59, in the reply filed on May 2, 2006 is acknowledged. Applicant argues that searching all the groups would not constitute a serious burden on the examiner. The examiner respectfully disagrees. The instant product claims are drawn to compositions comprising various components that embrace a vast array of potential embodiments. As was demonstrated in the restriction requirement, a search of the products is not coextensive with all the various methods by which they may be prepared. An additional search for these methods would constitute a serious burden.

The restriction requirement is still deemed proper and is therefore made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 12, 35, 36, 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims recite a formula wherein "the acylated cyclodextrin host molecule is about [(80% or 90%)] (wt.) to about 100% (wt.) substituted." It is not clear how a cyclodextrin can comprise 100% (wt.) substitution. No matter how highly substituted the cyclodextrin is, there remains some finite weight percent comprising the cyclooligosaccharide moiety itself. It appears

that what may be intended, and consistent with the specification is simply "about [80% or 90%] to about 100% substitution" without the (wt.) limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17, 19-22 and 26-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Uekama et al (US 5,904,929).

Uekama discloses medical devices (tablet and transdermal patch exemplified) comprising a polymer and an inclusion complex further comprising a pharmaceutically active agent and a peracylated cyclodextrin. See examples. The exemplified pharmaceutically active agents are isosorbide dinitrate (freely soluble) and triamcinolone (sparingly soluble).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 and 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uekama et al (US 5,904,929).

Uekama teaches as set forth above. The reference does not exemplify the full range of guest molecules. However, the reference teaches a wide variety of such molecules, including fragrances. See col 4-6. The reference further teaches the use of a wide variety of additives known in the art for the preparation of the devices taught therein. See col 6, lines 35-41.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the device(s) taught by Uekama using any of the guest molecules, including a fragrance molecule as expressly suggested by the reference with a reasonable expectation of success. It would be further within the scope of the artisan to use appropriate additives known in the art to prepare these products.

Claims 1-22 and 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uekama et al (US 5,904,929) in view of Rowe (US 6,616,650).

Uekama teaches as set forth above. The reference does not teach the full range of medical devices.

Rowe teaches the use of a balloon catheter coated with a composition comprising a therapeutic agent and a controlled release carrier, which may include a derivatized cyclodextrin. See col 2-3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a medical device such as a catheter using the acylated cyclodextrins taught by Uekama with a reasonable expectation of success. In the absence of unexpected results, one of ordinary skill would be motivated to incorporate such a cyclodextrin because Uekama teaches that they have utility as a drug release agent.

Claims 1-22 and 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uekama et al (US 5,904,929) in view of Tuch (US 5,624,411).

Uekama teaches as set forth above. The examples demonstrate the applicability of adsorbing the cyclodextrin inclusion product onto the surface of a polymer, such as polyethylene terephthalate. The reference does not teach the full range of medical devices.

Tuch teaches the preparation of drug eluting stents by adsorbing a solution of a drug solution onto the surface of a stent, which may be a bioadsorbable polymer, such as polyethylene terephthalate. See col 4.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a drug-eluting stent from a polymer, such as polyethylene terephtalate, and apply a solution of an acylated cyclodextrin/drug inclusion complex to the surface. One of ordinary skill would reasonably expect success in preparing such a product because Tuch had taught that polyethylene terephthalate is useful for the preparation of such a

stent, and Uekama had taught that acylated cyclodextrins have utility for the controlled release of drugs and are successfully applied to a polyethylene terephthalate surface.

Claims 1-22 and 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uekama et al (US 5,904,929) in view of Ledger et al (US 5,865,792) and further in view of Urtti et al (US 5,817,332).

Uekama teaches as set forth above. The reference does not teach the full range of polymers recited in the claims.

Ledger teaches the preparation of the preparation of transdermal drug delivery devices using a wide variety of polymers. The reference further suggests the use of cyclodextrins in the drug composition. See particularly abstract and col 9. Urtti demonstrates the applicability of cyclodextrins as drug delivery adjuvants in transdermal devices along with their use with a variety of polymers. See examples; col 4, lines 49-57; and col 5, lines 43-53.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the devices disclosed by Uekama using any polymers known in the art to have utility in preparing such a device. One of ordinary skill would reasonably expect success in using these polymers, particularly because Ledger had suggested their use in combination with a composition further comprising cyclodextrins with this application demonstrated by Urtti.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
July 18, 2006